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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

ERICA ANDRADE, Individually, and as Next Friend of Minor Child, Baby Girl A.A.,

Plaintiff(s),

v.

ABBOTT LABORATORIES, INC.,

Defendant.

Case No: 5:22-cv-02780

PLAINTIFF'S COMPLAINT & DEMAND FOR JURY TRIAL

Plaintiff, ERICA ANDRADE, Individually, and as Next Friend of Minor Child, A. A., ("Plaintiff"), hereby complains against Defendant Abbott Laboratories, Inc., ("Abbott") and alleges as follows:

Nature of the Case

1. This action is the result of the preventable death of a newborn baby, Baby Girl A.A., who died after developing a horrific and deadly disease caused (or substantially contributed to) by Abbott's cow's milk-based infant formula or fortifier.

2. Necrotizing Enterocolitis (hereinafter "NEC") is a deadly intestinal disease characterized by inflammation and injury of the gut wall barrier that can cause the tissue to necrose—or, in more simple terms, die—and can lead to perforation of the gut. Advanced cases of NEC often result in the need for abdominal surgery to remove the diseased portion of the gut and, in the most severe cases, NEC can cause death. Significantly higher rates of NEC have been found in premature or preterm babies with low birth weights[1] who are fed cow's milk-based formula or fortifier products.

3. Upon information and belief, the companies who manufacture these cow's milk-based formula or fortifier products, including Defendant Abbott, understand the relationship between consumption of their products and an increased risk that the preterm infant will develop NEC.

4. Nevertheless, upon information and belief, companies who manufacture these cow's milk-based formula or fortifier products, including Defendant Abbott, often intentionally mislabel and misrepresent the contents of the products both to the public at-

[1] For the sake of brevity, the terms "premature" and "preterm" will be used interchangeably throughout this Complaint.

large and to the health care community, including physicians like Baby Girl A.A.'s doctors, passing off these deadly products as something similar to or even superior to human breast milk.

5. Tragically, Baby A.A., who was premature at birth, was fed these cow's milk-based products, developed NEC, and died shortly thereafter.

6. Plaintiff, ERICA ANDRADE, Individually, and as Next Friend of Minor Child, A. A., brings this cause of action against Defendant Abbott for claims arising from the direct and proximate result of its misconduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, or sale of its cow's milk-based baby formula and fortifier products.

PARTIES

PLAINTIFF & BABY GIRL A.A.

7. Baby Girl A.A. was born prematurely at Community Hospital of Monterey Peninsula in Monterey, California, on March 23, 2013. Within an hour of her birth, she was transferred to UCSF Medical Center in San Francisco, California. She died on April 28, 2013, after developing NEC.

8. Baby Girl A.A. developed NEC after being fed Abbott's cow's milk-based products while in the Newborn Intensive Care Unit ("NICU") at UCSF Medical Center. For the duration of her short life, Baby Girl A.A. was a resident and citizen of the State of California.

9. Plaintiff, Erica Andrade, is the mother of Baby Girl A.A., and brings this action for the wrongful death of her daughter. Plaintiff, Erica Andrade, is a resident and

citizen of State of California, and resides in Seaside, California, in Monterey County.

DEFENDANT ABBOTT

10. Upon information and belief, Defendant Abbott manufactures, designs, formulates, tests, markets, labels, packages, sells, and otherwise places into the stream of commerce in the United States, including in California, cow's milk-based baby formula and fortifier products, including Similac Special Care.

11. Upon information and belief, Defendant Abbott is incorporated in Illinois, registered to conduct business in California, and can be served via its registered agent, CT Corporation System, at 330 N Brand Blvd, Ste 700, Glendale, California 91203.

JURISDICTION AND VENUE

12. This is a serious wrongful death case and the amount in controversy, exclusive of interest and costs, exceeds the $75,000.00 jurisdictional minimum.

13. This Court has jurisdiction over this case because Abbott markets, promotes, and sells products, including the product at issue in this case, in California, avails itself of the benefits and protections of the laws of California, and regularly transacts business in California. Additionally, many of the events which led to the untimely death of Baby Girl A.A. occurred in the State of California.

14. Venue of this action is proper because Abbott transacts substantial business California, a substantial number of the events giving rise to Plaintiff's claims occurred in California, and the corresponding documentary and testamentary evidence regarding Plaintiff's claims are, also, located in California.

FACTUAL ALLEGATIONS

A. The Science Connecting Cow's Milk-Based Products to NEC

15. According to the World Health Organization ("WHO"), babies born prematurely, or "preterm," are defined as being born alive before 37 weeks of pregnancy are completed, like Baby Girl A.A. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

16. Nutrition for preterm babies, especially those with a very low birth weight (under 1500 grams) or extremely low birth weight (under 1000 grams) like Baby Girl A.A., is significantly important. Because the United States ranks in the top ten countries in the world with the greatest number of preterm births, the U.S. market for infant formula and fortifiers is particularly vibrant.

17. Despite historical thinking that cow's milk-based products were good for the growth of premature, low-birth-weight babies, advances in science and research have proven just the opposite is true. Indeed, current science and research confirms strong links between cow's milk-based products and a significantly increased risk of developing NEC, which can cause death in premature infants, along with many other health complications and long-term risks to the infant. And contrary to Defendant Abbott's representations that their products were superior to human breast milk, advances in science show that, in reality, a human breast milk diet is superior to a formula-based diet.

18. As early as 1990, a prospective multicenter study on 926 preterm infants found that NEC was six to ten times more common in exclusively formula-fed babies than in those who were fed breast milk alone and three times more common than in those who

received formula plus breast milk. A. Lucas, T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519–23 (1990). This study also found that while NEC was rare in babies born at more than 30 weeks gestation whose diet included breast milk, it was 20 times more common in those fed cow's milk-based formula only. *Id.*

19. In a study published in 2007 it was reported: "The use of an exclusive HUM [Human] diet is associated with significant benefits for extremely premature infants <1259 g BW. The benefits include decreased NEC rates, mortality, late-onset sepsis, PDA, BPD, ventilator days, and ROP. Importantly, while evaluating the benefits of using an exclusive HUM-based protocol, it appears that there were no feeding-related adverse outcomes. This study demonstrates that an exclusive HUM diet provides important benefits beyond NEC." Hair, Amy, et al. *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet*. (Breastfeeding Medicine. 2016, Nov 2., 11(2):70-75.)

20. A separate study published in 2010 evaluated the health benefits of an exclusive human milk diet as compared to a diet with both human milk and cow's milk-based products in extremely premature infants. S. Sullivan, *et al.*, *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, JOURNAL OF PEDIATRICS, 156: 562-7 (2010). The results showed that preterm babies fed an exclusive human milk diet were ***90% less likely to develop surgical NEC*** as compared to a diet that included some amount of cow's milk-based products. *Id.* (emphasis added).

21. In 2011, the U.S. Surgeon General published a report titled, "The Surgeon

General's Call to Action to Support Breastfeeding." In it, the Surgeon General warned that "[f]or vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis (NEC)." Office of the Surgeon General, *The Surgeon General's Call to Action to Support Breastfeeding*, U.S. DEP'T OF HEALTH & HUMAN SERV., p.1 (2011), *available at* https://www.ncbi.nlm.nih.gov/ books/NBK52682/. This same report stated that premature infants who are not breast-fed are 138% more likely to develop NEC. *Id.* at 2.

22. Similarly, the American Academy of Pediatrics issued a 2012 policy statement that all premature infants should be fed an exclusive human milk diet because of the risk of NEC associated with the consumption of cow's milk-based products. A. Eidelman, *et al.*, *Breastfeeding and the Use of Human Milk*, PEDIATRICS, 129(3): e827–41 (2012). "The potent benefits of human milk are such that all preterm infants should receive human milk" and that "[i]f [the] mother's own milk is unavailable . . . pasteurized donor milk should be used." *Id.* at e831.

23. A study published in 2013 showed that every one of the 104 premature infants receiving an exclusive human-milk-based diet exceeded targeted growth standards, as well as length, weight, and head circumference gain. The authors concluded that "this study provides data showing that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive human milk-based diet." A. Hair, *et al*, *Human Milk Feeding Supports Adequate Growth in Infants ≤1250 Grams Birthweight*, BMC RESEARCH NOTES, 6:459 (2013). This is a clear indication that inadequate growth is a poor excuse for prioritizing cow's milk-based formula over human breast milk, but the practice continued largely due to extensive, aggressive marketing

campaigns conduct by infant formula companies.

24. Multiple scientific studies throughout the 2010s overwhelmingly concluded that the risks of NEC are increased by the consumption of cow's milk-based products and decreased by an exclusive human milk diet.

25. In 2013, the first randomized trial in extremely premature infants of human milk versus preterm cow's milk-based formula found a significantly higher rate of surgical NEC in infants receiving the cow's milk-based preterm formula and supported the use of an exclusive human milk diet to nourish extremely preterm infants in the NICU. E.A. Cristofalo, *et al*, *Randomized Trial in Extremely Preterm Infants*, J PEDIATR., 163(6):1592–95 (2013).

26. A 2014 study reported that NEC is a devastating disease of premature infants associated with significant morbidity and mortality, and while the pathogenesis of the disease remains incompletely understood, it is well established that the risk of NEC is increased by the administration of infant formula and decreased by the administration of breast milk. Misty Good, *et al*., *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*, EXPERT REV. CLIN. IMMUNOL., 10(7): 875–84 (2014). The same study found that NEC "is the ***most frequent and lethal*** gastrointestinal disorder affecting preterm infants and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death. *Id.* (emphasis added). "NEC affects 7–12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies. *Id.* The typical patient who develops NEC is a premature infant who displays a rapid

progression from mild feeding intolerance to systemic sepsis, and ***up to 30% of infants will die from this disease***." *Id.* (emphasis added). The study concluded that advances in formula development have made it possible to prevent NEC, and the "exclusive use of human breast milk is recommended for all preterm infants and is associated with a significant decrease in the incidence of NEC." *Id.*

27. In another study published in 2014, it was reported that an exclusive human milk diet, devoid of cow's milk-based products, was associated with lower risks of death, NEC, NEC requiring surgery, and sepsis in extremely preterm infants without compromising growth and should be considered as an approach to nutritional care of these infants. Steven Abrams, *et al.*, *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, BREASTFEEDING MED., 9(6):281–86 (2014). This study concluded that the use of an exclusive human milk-based diet, using a nutritionally appropriate human milk-based fortifier, was the best option for extremely preterm infants. *Id.* at 286.

28. In 2016, a large study supported previous findings that an exclusive human milk diet in extreme preterm infants dramatically decreased the incidence of both medical and surgical NEC. A. Hair, *et al*, *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk Based Diet,* BREASTFEEDING MED., 11(2): 70–74 (2016). This was the first study to compare rates of NEC after a feeding protocol implementation at multiple institutions and years of follow-up using an exclusive human milk diet. The authors concluded that the use of an exclusive human milk diet is associated with significant benefits for extremely preterm infants and found that an

exclusive human milk-based protocol produced no feeding-related adverse outcomes. *Id.* at 74.

29. A 2017 study reported that human milk is the preferred diet for preterm infants, protecting against a multitude of NICU challenges and especially NEC. D. Maffei and R. Schanler, *Human milk is the feeding strategy to prevent necrotizing enterocolitis!*, SEMINARS IN PERINATOLOGY, 41(1):36–40 (Feb. 2017). The study found that infants who receive greater than 50% of their mother's breast milk in the two weeks after birth have a significantly decreased risk of NEC and that a factor in declining rates of NEC was the increased utilization of donor human milk. *Id.* at 36. "Preterm infants are susceptible to NEC due to the immaturity of their gastrointestinal and immune systems. An exclusive human milk diet compensates for these immature systems in many ways such as lowering gastric pH, enhancing intestinal motility, decreasing epithelial permeability, and altering the composition of bacterial flora." *Id.* The study concluded that preterm infants should ideally be fed human milk and avoid bovine protein, adding that human milk-based fortifiers "can provide additional nutritional supplements necessary for adequate growth." *Id.*

30. A 2017 publication by the American Society for Nutrition noted that human milk has "been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC." Jocelyn Shulhan, *et al*, *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, ASN ADV. NUTR., 8(1):89 (2017). This study compared the results from two randomized clinical trials on preterm infants with severely low weight (between 500 and 1250 grams

at birth) and compared the effect of cow's milk-based preterm infant formula to human milk on rates of NEC occurrence. Both trials found that an exclusive human milk diet resulted in a much lower incidence of NEC. *Id.* at 87–89. While the study noted that cow's milk-based preterm formulas provided consistent calories and were less expensive than human milk-based products in the short-term, the cow's milk-based products ***significantly increase the risk of NEC and death***. *Id.* at 84, 89. The long-term health care costs associated with NEC, however, were exorbitant—from 2011 to 2012, the cost of NEC in the U.S. ranged between $180,000 and $198,000 per infant and nearly doubled to $313,000 per infant in cases of surgically treated NEC. *Id.* at 82. Further, NEC survivors accrue substantially higher outpatient costs. *Id.* at 82.

B. Abbott's Strategy to Conceal the Dangers of Its Cow's Milk-Based Formulas From Healthcare Providers and Parents

31. Recognizing a shift in the medical community towards an exclusive human milk-based diet for preterm infants, upon information and belief, Abbott began heavily promoting "human milk fortifiers," a name which suggests the product is derived from human milk. But it is not. Abbott's human milk fortifiers were, in fact, still cow's milk-based products.

32. Upon information and belief, Abbott also designed competing, ongoing, systematic, and misleading marketing campaigns to persuade physicians and parents to believe that: (1) Cow's Milk-based formula and fortifiers are safe; (2) Cow's Milk-Based Products are equal, or even superior, substitutes to breastmilk; and (3) physicians should consider their Cow's Milk-Based Products a first choice.

33. To further disseminate these messages throughout the scientific and medical community, upon information and belief, Abbott provided substantial monetary support to various organizations, purportedly dedicated to the research and study of relevant infant health topics, like dietetics and nutrition.

34. Upon information and belief, Abbott used its positions of prominence and power in these organizations to ghostwrite favorable publications and to silence dissenting scientific voices that might reveal the true risks associated with consuming products like Abbott's, which were derived from cow's milk.

35. Similarly, upon information and belief, Abbott marketed its products for preterm infants as necessary for growth, and perfectly safe for preterm infants, despite knowing this was untrue and unsupported by the data.

36. Thus, despite the existence of alternative and safe human milk-based fortifiers—some of which are actually made by Abbott—, Abbott, at all relevant times, and to this day, continues to market or to sell its Cow's Milk-Based Products, claiming they are safe and failing to alert healthcare professionals and parents of the significant health risk posed by ingesting these products, especially to preterm, low weight infants like Baby Girl A.A.

37. Upon information and belief, Abbott's marketing and public relations campaigns, which touted the safety, necessity, and superiority of their cow's milk-based products were motivated, at least in part, by a desire to create brand loyalty amongst doctors and parents, and ultimately to profit from the sale of their infant formula products.

38. Upon information and belief, Abbott's misinformation campaigns were incredibly successful.

39. Indeed, The World Health Organization's 2018 Status Report on this issue noted that "despite ample evidence of the benefits of exclusive and continued breastfeeding for children, women, and society, far too few children are breastfed as recommended." *Marketing of Breast-milk Substitutes: Nat'l Implementation of the Int'l Code, Status Report 2018*, Geneva: World Health Org., p.2 (2018). "[A] major factor undermining efforts to improve breastfeeding rates is continued and aggressive marketing of breast-milk substitutes," noting that in 2014, the global sales of breast-milk substitutes amounted to $44.8 billion was expected to rise to $70.6 billion by 2019. *Id.*

40. The WHO's most recent Status Report in 2020, again, took issue with these aggressive marketing tactics, recommending that legislators "recognize their obligations, both under international human rights law and international agreements, to promote and protect breastfeeding, and to eliminate inappropriate marketing practices" because "far too few countries have legal measures in place to effectively stop harmful marketing of [breast-milk substitutes]." *Marketing of Breast-milk Substitutes: Nat'l Implementation of the Int'l Code, Status Report 2020*, Geneva: World Health Org., pp. viii, 26 (2020). The WHO also criticized "[m]anufacturers and distributors of [breast-milk substitutes]" for continuing to "target health workers for promotion of their products." *Id.* at 23.

C. Mead and Abbott Did Not Warn Doctors or Parents That Their Cow's Milk-Based Products Were Dangerous

41. Upon information and belief, at all relevant times and to this day, Defendant Abbott promotes the use of its cow's milk-based products to parents, physicians, hospitals, and

medical providers as safe and, specifically, necessary to help promote adequate growth in premature infants.

42. But Abbott knows all three claims are untrue, upon information and belief.

43. Indeed, at all times relevant hereto, Abbott was aware that its cow's milk-based products significantly increased the risk that any premature infant, like Baby Girl A.A., could develop NEC (and even die) as a result, upon information and belief.

44. Despite understanding that its products significantly increased the risk of developing NEC, Abbott deliberately chose to omit a specific warning regarding this risk.

45. Defendant's cow's milk-based products do not include any instructions or warnings detailing the risks of NEC presented by the product, namely that ingestion of cow's milk-based product significantly increases the risks of NEC and, consequently, of death.

46. In fact, Abbott does not provide any warning whatsoever—in its labeling, websites, or other marketing or promotional materials—that its cow's milk-based products exponentially increase the risks of NEC and death in preterm infants, or that human breast milk, donor breast milk, and human breast milk-based fortifiers are much safer for preterm babies than its cow's milk-based products.

47. Abbott also does not provide any detailed instructions on how to more safely use the product, such as instructions on when and how to feed preterm infants, so as to avoid an increased risk of NEC and death when using its Similac product.

48. For example, Abbott's Similac product contained only the following packaging information guidelines, instructions and warnings:

"Similac Special Care 24 – Precautions:

- Very low-birth weight infants are particularly susceptible to gastrointestinal complications; therefore, feeding should be initiated cautiously
- Tolerance to enteral feedings should be confirmed by initially offering small volumes of formula followed by cautious progression to higher caloric feedings
- Spitting up, abdominal distention, abnormal stools or stool patterns, excessive gastric residuals, or other signs of intestinal dysfunction have been associated with enteral feeding before the intestinal tract is ready to accommodate the regimen. At the first sign of these problems, enteral feeding should be slowed or discontinued
- Not intended for feeding low-birth-weight infants after they reach a weight of 3600 g (approximately 8 lb) or as directed by a physician"

D. Circumstances of Baby Girl A.A.'s Death

49. Baby Girl A.A. was born prematurely, at 26 weeks gestation, at Community Hospital of Monterey Peninsula, in Monterey, California on March 23, 2013. At birth, Baby Girl A.A. weighed less than 1000 grams.

50. After she was born, Baby Girl A.A. was transferred to UCSF Medical Center, where she was examined and admitted to the NICU.

51. Notably, at that time, her medical records indicate the absence of any signs and symptoms of NEC.

52. At first, Baby Girl A.A. was fed donor breast milk. With the exception of a brief period of time on April 8, 2013, Baby Girl A.A. continued to receive only donor breast milk until April 15, 2013.

53. On April 15, 2013, her doctors ordered that Baby Girl A.A. begin weaning off breast milk and transitioning Abbott's cow's milk-based formula. She began receiving feedings which consisted of 50% donor breast milk and 50% Similac Special Care 24 K/cal.

54. A few days later, her doctor ordered that she receive Abbott's Similac Special Care 27 K/cal—another cow's milk-based formula.

55. Four days later, Baby Girl A.A. developed NEC, which was visible based on her increased abdominal girth, and confirmed by abdominal x-rays taken that day.

56. Upon information and belief, Baby Girl A.A. needed surgery to remove the rotting portion of her bowel, but her surgeons determined she was too unstable to undergo the procedure. Her NEC continued to progress over the next week.

57. Tragically, Baby Girl A.A. succumbed to her injuries and was pronounced dead on April 28, 2013, at 10:52 p.m. She was barely one month old.

58. Notably, her physicians at the time determined NEC was the immediate cause of her death.

59. Plaintiff, Erica Andrade—Baby Girl A.A.'s mother—was unaware of the fact that Abbott's cow's milk-based formulas, including but not limited to Similac Special Care 24 K/cal and Similac Special Care 27 K/cal, fed to Baby Girl A.A. were capable of causing NEC.

60. Had Plaintiff been made aware of the facts, data, and science that linked Abbott's Similac Special Care 24 K/cal and Similac Special Care 27 K/cal and other cow's milk-based products to an increased risk of NEC, she would have insisted on donor breast milk, would have breast fed her child, requested a different formula, or would have refused Similac feedings.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

61. Abbott willfully, wantonly, intentionally conspired, and acted in concert to

withhold information from Plaintiff, Baby Girl A.A.'s healthcare providers, and the public concerning the known hazards associated with the use of and exposure to cow's milk-based formulas.

62. Abbott willfully, wantonly, intentionally conspired, and acted in concert to withhold safety-related warnings from Plaintiff, Baby Girl A.A.'s healthcare providers, and the public concerning the known hazards associated with the use of and exposure to cow's milk-based formulas.

63. Abbott willfully, wantonly, intentionally conspired, and acted in concert to withhold appropriate feeding instructions from the Plaintiff, Baby Girl A.A.'s healthcare providers, and the public concerning the known hazards associated with the use of and exposure to cow's milk-based formulas.

64. Upon information and belief, Abbott willfully, wantonly, intentionally conspired, and acted in concert to ignore relevant safety concerns and deliberately not study the safety and efficacy of cow's milk-based formulas.

65. Upon information and belief, Abbott willfully, wantonly, intentionally conspired, and acted in concert to call into question scientific and medical literature that disputed or otherwise undermined its primary message that cow's milk-based formula was safe.

66. Due to the absence of any warning by Abbott as to the significant health and safety risks posed by its cow's milk-based infant formula, Plaintiff was unaware that Similac could cause serious injuries, including NEC, as this danger was not known to Plaintiff or the general public.

67. Given the foregoing, Abbott is estopped from relying on any statute of limitations defenses.

COUNT I: STRICT LIABILITY — DESIGN DEFECT

68. Plaintiff incorporates by reference each paragraph of this Complaint as if fully set forth herein and further alleges as follows:

69. At all times material to this action, Defendant Abbott was engaged in the sale, or marketing or design, or manufacture, or distribution of Cow's Milk-Based Products, which are defectively designed or unreasonably dangerous to consumers, including Baby Girl Baby Eli.

70. Defendant Abbott, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

71. At all times material to this action, the Cow's Milk-Based Products manufactured, distributed or sold by Defendant Abbott, were in a defective or unreasonably dangerous condition at the time the products were placed in the stream of commerce for nutritional use for preterm infants.

72. Defendant Abbott specifically marketed and created its Cow's Milk-Based Products for use as nutrition and nutritional supplements for preterm infants, like Baby Girl A.A.

73. Defendant Abbott's Cow's Milk-Based Products are expected to and do reach the user without substantial change affecting that defective or unreasonably dangerous condition.

74. Prior to Baby Girl A.A.'s death in April 2013, Defendant Abbott was aware or should have been aware that its Cow's Milk-Based Products were not safe for use, as they were used, with nutrition or nutritional support in preterm infants, yet took no steps to prevent the use of these products in such situations.

75. Defendant Abbott knew or should have known that the use of its Cow's Milk-Based Products with preterm infants was unreasonably dangerous in that its Cow's Milk-Based Products significantly increased the risk of NEC and death.

76. Furthermore, scientific data and well-researched studies have concluded that the Cow's Milk-Based Products of the Defendant carried unreasonable risks of NEC and death, which far outweighed the products' benefits for preterm infants like Baby Girl A.A.

77. Despite the foregoing, the Defendant continued to sell and market its defective or unreasonably dangerous products to preterm infants.

78. The products were defectively designed or unreasonably dangerous, including, but not limited to the following particulars:

a. The products did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner, such that the use of Cow's Milk-Based Products as nutrition or nutritional supplements in preterm infants significantly increased the risk of NEC and death;

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants, such as

Baby Girl A.A, to risks of serious bodily injury and death;

c. The products failed to meet legitimate, commonly held, minimum safety expectations of that product when used in an intended or reasonably foreseeable manner;

d. Defendant failed to utilize economical and technically available safer design alternatives for preterm infant formula and fortifiers;

e. The products were manifestly unreasonable in that the risk of harm so clearly exceeded the products' utility that a reasonable consumer, informed of those risks and utility, would not purchase the product;

f. Defendant failed to adopt an adequate or sufficient quality control program; or

g. Defendant failed to inspect or test its products with sufficient care.

79. As a direct and proximate cause of the Cow's Milk-Based Product's unreasonably dangerous condition, Baby Girl A.A. suffered serious bodily injuries, including developing NEC, lived for several days with this painful condition, and ultimately died.

WHEREFORE, Plaintiff demands judgment against Defendant Abbott for all applicable wrongful death damages, costs of this action, post-judgment interest, and trial by jury.

COUNT II: STRICT LIABILITY — FAILURE TO WARN

80. Plaintiff incorporates by reference each paragraph of this Complaint as if fully set forth herein and further alleges as follows:

81. Defendant Abbott, as the manufacturer or seller of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiff in particular, to properly warn and provide adequate warnings or instructions about the dangers and risks associated with the use of Cow's Milk-Based Products with preterm infants, specifically including but not limitedto the risk of NEC and death.

82. Defendant Abbott, as the manufacturer or seller of Cow's Milk Product, was unreasonable in relying upon any intermediary, including physicians, other health care providers or health care staff, to fully warn the end user of the hidden dangers and risks in its Cow's Milk- Based Products, as the magnitude of the risk involved is using Defendant's Cow's Milk-Based Products with preterm infants is significant and involves the real danger of serious bodily injury and death.

83. Defendant Abbott, as the manufacturer or seller of Cow's Milk Products, oweda duty to fully warn and instruct any intermediary, including physicians, other health care providers or health care staff, of the significant dangers of its Cow's Milk-Based Products.

84. Defendant owed a duty to provide warnings and instructions on its Cow's Milk- Based Products marketed or sold for use with preterm infants that adequately communicated information on the dangers and safe use of the product to health care providers and staff using these products in a NICU, taking into account the characteristics of, and the ordinary knowledge common to, such prescribing health care providers and administering health care staff and to specifically warn of the risks and danger associated with the use of Cow's Milk-Based Products with preterm infants,

specifically including but not limited to the risk of NEC and death.

85. But rather than provide adequate warnings, Defendant Abbott developed relationships, which included financial incentives to health care providers and facilities for using its Cow's Milk-Based Products within the NICU, such that health care providers and facilities had anincentive to withhold any instructions or warnings from the end user, upon information and belief.

86. Additionally, or in the alternative, if healthcare providers and health care staff had been properly instructed and warned of the risks associated with the use of Cow's Milk-Based Products with preterm infants, they would have not used such a dangerous product.

87. Defendant Abbott, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

88. Defendant Abbott, through its own testing and studies, consultants and experts, or knowledge of the scientific literature, as set forth above, knew of the significant risk of NEC with preterm infants and death.

89. Defendant Abbott, through its knowledge, review, and survey of the scientific literature, as detailed above, knew that the use of Cow's Milk-Based Products with preterm infants could cause severe injury, including but not limited to NEC and death.

90. Defendant Abbott breached the foregoing duties and failed to provide proper warnings or instructions of its Cow's Milk-Based Products, including but not

limited to the following acts:

a. Providing **no warnings** regarding the risk of NEC and death;

b. Providing inadequate labeling that failed to warn of the risks of use of Cow's Milk-Based Products with preterm infants, including but not limited to NEC;

c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed its products to preterm infants in order to decrease the risk of NEC or death;

d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of the Defendant's Cow's Milk Product;

e. Failed to provide instructions to consumers and health care providers that the Defendant's products carried a significant risk that its Cow's Milk-Based Products exponentially increased their baby's risk of developing NEC and death;

f. The warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct on certain conditions, but do not warn that the use of Cow's Milk-Based Products significantly increasing the risk of NEC and death, and they fail to provide any details on how to avoid such harm;

g. Failed to contain a large and prominent "black box" type warning that its Cow's Milk-Based Products are known to significantly increase the risk of NEC and death when compared to Human Milk in preterm infants;

h. Failed to provide well researched and well-established studies that linked its Cow'sMilk-Based Products to NEC and death in preterm infants;

i. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of its products;

j. Failed to otherwise warn physicians, and healthcare providers of the extreme risks associated with feeding preterm infants Cow's Milk-Based Products;

k. Failed to send out "Dear Doctor" letters warning of the risks of NEC and death and thecurrent scientific research and data to better guide the hospitals and physicians to better care for the extremely preterm infants;

l. Failed to advise physicians and healthcare providers that Cow's Milk-Based Products are not necessary to achieve growth and nutritional targets for preterm infants; or

m. Failed to contain sufficient instructions and warnings on the Cow's Milk-Based Products such that health care providers and health care staff were not properly warned of the dangers of NEC with use of Cow's Milk-Based Products and preterm infants.

91. As a direct and proximate result of Defendant Abbott's failure to warn or properly instruct, Baby Girl A.A. suffered serious bodily injuries, including developing NEC, lived for several days with this painful condition, and ultimately died.

WHEREFORE, Plaintiff demands judgment against Defendant Abbott for all applicable wrongful death damages, costs of this action, post-judgment interest, and trial by jury.

COUNT III: NEGLIGENCE

92. Plaintiff incorporates by reference each paragraph of this Complaint as if fully set forth herein and further alleges as follows:

93. Defendant Abbott, as the manufacturer or seller of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiff in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute products free of unreasonable risk of harm to users and patients, when said product is used in its intended manner.

94. Defendant Abbott, as a manufacturer, has a duty to hold the knowledge and skill of an expert, and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

95. Defendant Abbott, directly or indirectly, negligently, or defectively made, created, manufactured, designed, assembled, tested, marketed or sold the subject Cow's Milk-Based Products.

96. Defendant breached the duty owed to Plaintiff and acted negligently in its actions,including, but not limited to, the following:

a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in a foreseeable and intended manner;

b. The products contained hidden and dangerous design defects and were not

reasonably safe as intended to be used, subjecting preterm infants to risks of seriousbodily injury and death in that the products' design or manufacture amounted to or resulted in a defect failure mode of the products;

c. Failing to collect data to determine if its products were safe for preterm infants; Failing to collect data to determine when and how its products could be used safely;

d. Failing to utilize the significant peer reviewed research to develop instructions;

e. Failing to develop evidence-based guidelines or instructions to decrease the risk of its products causing NEC and death;

f. Failing to provide evidence-based guidelines or instructions to decrease the risk ofits products causing NEC and death;

g. Failing to stop or deter its products from being fed to extremely preterm infants like Baby Girl A.A.;

h. Failing to provide evidence-based instructions or guidance on when or how a preterm infant should be transitioned to the products;

i. Failing to continuously and vigorously study its cow's milk-based products in orderto avoid NEC and death in premature infants;

j. Failing to utilize economical and technically available safer manufacturing or design alternatives for the preterm infant formula and fortifier;

k. Failing to adopt an adequate or sufficient quality control program; or

l. Failing to inspect or test its products with sufficient care.

97. Defendant Abbott knew or should have known that its products were to be used asnutrition and nutritional supplements with preterm infants, like Baby Girl A.A.

98. Defendant Abbott knew or should have known that the use of its Cow's Milk-Based Products with preterm infants was unreasonably dangerous in that its Cow's Milk-Based Productssignificantly increased the risk of NEC and death.

99. Furthermore, scientific data and well researched studies have concluded that the Cow's Milk-Based Products of the Defendant carried unreasonable risks of NEC and death, which far outweighed the products' benefits for premature infants like Baby Eli.

100. As a direct and proximate result of Defendant Abbott's failure to warn or properly instruct, Baby Girl A.A. suffered serious bodily injuries, including developing NEC, lived for several days with this painful condition, and ultimately died.

WHEREFORE, Plaintiff demands judgment against Defendant Abbott for all applicable wrongful death damages, costs of this action, post-judgment interest, and trial by jury.

COUNT IV: VIOLATION OF THE ILLINOIS UNIFORM DECEPTIVE TRADE PRACTICES ACT

27. Plaintiff incorporates by reference each paragraph of this Complaint as if fully set forth herein and further alleges as follows:

28. At all times relevant, the Illinois Uniform Deceptive Trade Practices Act ("Illinois UDTPA") prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices, including . . . misrepresentation or the concealment, suppression or omission

of any material fact, with the intent that others rely upon the concealment, suppression or omission of such material fact." 815 Ill. Comp. Stat. Ann. 505/2.

29. Upon information and belief, as discussed herein, Abbott, at all relevant times, engaged in unfair and deceptive acts by concealing and omitting significant and material facts in connection with their labeling, advertisement, and sale of its cow's milk-based infant formulas, including Similac.

30. Upon information and belief, as discussed herein, Abbott, at all relevant times, misrepresented the benefits of cow's milk-based infant formulas, including Similac, by omitting significant and material facts in its marketing, promotion, sale, and labeling of its cow's milk-based infant formulas, including the fact that its cow's milk-based infant formulas significantly increased the risk of developing NEC. In fact, the entire time Baby Girl A.A. was prescribed and ingested Abbott's cow's milk-based infant formula, the label (and corresponding advertisements and marketing materials) contained no warnings concerning NEC at all.

31. Instead of including applicable warnings or appropriate instructions, Abbott misleadingly advertised only the purported benefits of cow's milk-based infant formulas, but did not disclose any risks relative to NEC. Indeed, Abbott did not disclose any warnings associated with use of the product, including, but not limited to, the increased risk of developing NEC, which could lead to severe complications including death.

32. Upon information and belief, Abbott's advertisements and marketing materials concerning cow's milk-based infant formulas, including Similac, which were created and disseminated by Abbott, were intended to induce healthcare providers to

prescribe cow's milk-based infant formulas, including Similac, and parents to feed their infants cow's milk-based infant formulas, including Similac.

33. And indeed, Baby Girl A.A.'s parents and her healthcare providers detrimentally relied on the information contained in Abbott's labeling, advertising, and other marketing materials. Such statements though, in reality, deceptive and untrue formed, at least in part, the basis of Baby Girl A.A.'s physicians' decision to recommend and prescribe a cow's milk-based infant formula, like Similac, as well as the decision of Plaintiff—Baby Girl A.A.'s mother—to permit her infant to be fed a cow's milk-based infant formula, like Similac.

34. Such advertisements and statements with respect to cow's milk-based infant formulas, including Similac, were misleading, demonstrably false, and violated the Illinois UDTPA.

35. As a result of violating the Illinois UDTPA, Abbott caused Baby Girl A.A.'s doctors to prescribe cow's milk-based infant formulas, including Similac, and Baby Girl A.A. to ingest cow's milk-based infant formulas, including Similac, which caused severe injuries and damages as previously described herein.

36. Additionally, and in the alternative, as a result of violating the Illinois UDTPA, Abbott also caused Baby Girl A.A.'s injuries to be more severe than they otherwise would have been, if Baby Girl A.A.'s doctors had been given appropriate instructions, adequate safety information, and been advised to stop formula feeds, seek medical treatment, or medical intervention sooner.

37. Accordingly, Plaintiff is entitled to damages under the Illinois UDTPA.

COUNT V: VIOLATION OF THE CALIFORNIA UNFAIR COMPETITION LAW

101. Plaintiff repeats, reiterates, and incorporates by reference every allegation of this Complaint contained in each of the foregoing paragraphs.

102. At all times relevant, the California Unfair Competition Law ("UCL") prohibits "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by Chapter 1 (commencing with Section 17500) of Part 3 of Division 7 of the Business and Professions Code" and declares such acts or practices "unfair competition."

103. Upon information and belief, as discussed herein, Defendant Abbott, at all relevant times, made false and misleading representations concerning Similac.

104. Upon information and belief, as discussed herein, Defendant Abbott, at all relevant times, omitted material facts in its marketing, promotion, and sale of Similac.

105. More specifically, for example, Defendant Abbott communicated only the purported benefits of Similac and touted it as a product "superior" to breast milk, while failing to disclose any warnings associated with use of the product, including, but not limited to, the increased risk of developing NEC and death.

106. Such representations and omissions were intended to induce healthcare providers to prescribe Similac and parents to ask for and give their infants Similac.

107. Such representations violated the California UCL.

108. As a result of violating the California UCL, Defendant Abbott caused Baby Girl A.A. to be prescribed and to ingest Similac, causing her severe personal injuries and,

ultimately, leading to her death.

109. Plaintiff is, therefore, entitled to restitution under the UCL.

PRAYER FOR RELIEF

38. Plaintiff respectfully requests the following damages be considered separately and individually for the purpose of determining the sum of money that will fairly and reasonably compensate Plaintiff:

a. Baby Girl A.A.'s medical expenses, physical pain and suffering, and other compensatory damages to be proven at trial;

b. Damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, loss of consortium, and other non-economic losses sustained as a result of Abbott's conduct;

c. Past, present, and future out-of-pocket costs, lost income, revenue, profits, or business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended for Plaintiff;

d. Attorney's fees, expenses, and recoverable costs incurred in connection with this action;

e. Plaintiff's Loss of Enjoyment of Life;

f. Pre- and Post-Judgment Interest;

g. Exemplary and Punitive Damages;

h. Treble Damages; and

i. Such other relief to which Plaintiff may be justly entitled.

DEMAND FOR JURY TRIAL

Plaintiff hereby request a trial by jury on all issues triable by jury.

Dated: May 11, 2022

MARTIN | BAUGHMAN, PLLC

By: _____

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